

REMARKS

State of the Claims

Claims 1-18 are pending. Claim 2 has been canceled without prejudice. Claim 1 now contains the canceled subject matter of now canceled Claim 2. Claims 1, 3-18 remain. No new matter has been added.

35 U.S.C. § 112 Rejection

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph, because the Examiner asserts that the specification, while being enabling for the addition of an “asparagines-reducing enzyme” (i.e., asparaginase), does not reasonably provide enablement for any random method reaction of “reducing the level of asparagines” in a cocoa beans.

Applicants have amended Claim 1 to include the subject matter of now canceled Claim 2. An affirmative process has been added to Claim 1, namely, “adding an asparagine-reducing enzyme to cocoa beans.” Applicants respectfully contend that by adding an affirmative step to the functional result achieved (i.e., the reduction of asparagine in cocoa beans), that now-amended Claim 1 overcomes the Examiner’s rejection.

Therefore, Applicants request reconsideration and allowance of Claim 1 over the Examiner’s 35 U.S.C. § 112, first paragraph, rejection.

Claims 2-13 and 17-18 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

The Examiner states that the term “reduced” in Claims 5-13 and 17 is indefinite. The Examiner further states that the term ‘reduced’ “is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.”

Applicants respectfully disagree with the Examiner’s assertions. First, Applicants point out that the claims alone do not have to define the term “reduced”. Rather, the specification can provide the proper basis for definition of any term used in the claim. Applicants assert that the specification does in fact provide the proper definition and understanding of the term “reduced” as it relates both to asparagine-reduction and acrylamide-reduction.¹

¹ Applicants’ Specification, page 3, lines 8-10: “Accordingly, acrylamide formation in roasted cocoa beans can be reduced by removing the asparagine or converting the asparagine in the cocoa beans to another substance before final roasting of the beans.” [Emphasis added.]

In addition, common usage of a term can provide definition for claim terms. For example, the term “reduced”, in common usage, is defined as “to lessen in extent, amount, number, degree or price.” The American Heritage Dictionary, 2nd Ed., Houghton Mifflin Company, Boston (1991). Such definition bolsters Applicants’ use of the term in their specification since Applicants teach the reduction of the amount of acrylamide in cocoa beans in comparison to cocoa beans not treated for such acrylamide reduction.

Whether one skilled in the art looks to the specification or to common usage, it would be obvious to one skilled in the art that the term “reduced,” as used in the presently rejected claims, means that the level of asparagine/acrylamide is less in treated cocoa beans than it would ordinarily be in untreated cocoa beans, i.e. cocoa beans not exposed to asparagine-reducing enzymes. Thus, the term “reduced” means that the cocoa beans have been treated with an enzyme such that the level of asparagine/acrylamide is less than what it would be in untreated cocoa beans.

Applicants respectfully assert that one skilled in the art would understand that the use of the term “reduced” in the present claims describes the level of asparagine or acrylamide in treated cocoa beans as compared to the level present in untreated cocoa beans. Therefore, it is respectfully asserted that the term “reduced” in the presently rejected claims does indeed provide a standard for ascertaining the meaning, such that one skilled in the art would be reasonably apprised of the scope of the claimed invention.

As such, Applicants respectfully request reconsideration and allowance of Claims 2-13 and 17-18 over the Examiner’s 35 U.S.C. § 112, second paragraph, rejection.

Claims 2-4 stand rejected over the Examiner’s 35 U.S.C. § 112, second paragraph, rejection. Specifically, the Examiner states that asparagine is “not an actual oxido-reductase class of enzymes,” but rather, belongs to the hydrolase class of enzymes. The Examiner continues by saying that “while Applicant presumably intends this term to broadly encompass any enzyme which reduces the amount of asparagine in the product, it is technically improper.” Finally, the Examiner concludes by quoting Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350 (Fed Cir. 1999) which says that where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term.

Applicants respectfully traverse this rejection. The term “reducing,” as used within the phrase “asparagine-reducing enzyme,” refers not to a class of enzymes, but rather to their functionality. Moreover, contrary to the Examiner’s contention, the term “asparagine-reducing enzyme” is fully defined

in the present specification. Specifically, in the present specification, both of the foregoing concerns are addressed as the term “asparagine-reducing enzyme” is defined as “any enzyme capable of reducing the *level* of asparagine in cocoa beans.”² [Emphasis added.] There is no mention of enzyme class or reduction reactions, such that one skilled in the art would be misled as to the meaning of the term as the Examiner claims. Indeed, in light of the foregoing definitions, Applicants respectfully assert that “asparagine-reducing enzyme” is clearly defined in the present specification such that one skilled in the art would understand that “asparagine-reducing” relates to the level of asparagine rather than the class of the enzyme described therein. For these reasons, Applicants respectfully traverse the Examiner’s rejection of the use of the term “asparagine-reducing enzyme” under the second paragraph of §112.

Therefore, Applicants respectfully request reconsideration and allowance of Claims 1-5 and 7-10 over the Examiner’s 35 U.S.C. § 112, second paragraph, rejection.

Claim 18 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner states that the term “low” used herein is a relative term which renders the claims indefinite. The Examiner states that the term “low” is not defined by the claims, that the specification does not provide a standard for ascertaining the requisite degree, and that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Lastly, the Examiner states that there is no standard or original amount of acrylamide provided in the specification such that one skilled in the art (or a consumer of the claimed article) would be apprised of what constituted a “low” amount of acrylamide within the article.

Applicants respectfully disagree with the Examiner. First, Applicants point out that Claim 18 is an article of commerce claim and as such claims the communication of a “low” level of acrylamide in the cocoa beans. Such a communication is amply supported by the specification.³

In Claim 18, the message informs the consumer that the cocoa beans are low in acrylamide. Applicants assert that one of skill in the art would, by the claims themselves and from Applicants’ specification, understand that the invention is an article of commerce that has as part of its packaging or advertising a message communicating the “low”-ness of acrylamide and the reduction thereof. Applicants further assert that a consumer reading this message would understand what this “low”-ness is intended to convey without, as the Examiner puts it, providing “a standard for ascertaining the requisite degree” of the “low”-ness of the acrylamide.

² Id. at page 5, lines 26-27.

³ Id. at page 8, lines 28-36 to page 9, lines 1-8.

Furthermore, Applicants respectfully point out that the term “low” as used in claim 18 is simply a word on a label, and thus, there is no definiteness issue surrounding its use in this context. A label either displays the term “low,” or a similar term, or it doesn’t. Therefore, because the presently rejected claim relates only to the labeling of the product, rather than the potato products, it is irrelevant what the term “low” actually means in these claims. (It will be left to the appropriate regulatory body to determine whether the use of the term “low” on a label, as claimed herein, is proper).

Thus, Applicants respectfully assert that the Examiner’s rejection of Claim 18 should be obviated and allowed to issue over the Examiner’s 35 U.S.C. § 112, second paragraph, rejection.

35 U.S.C. § 103 Rejection

Claims 1-18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Elder, et al. (U.S. Patent Application No. 2004/0058054--hereinafter, Elder ‘054).

The Examiner states that Elder ‘054 discloses “a method for reducing the amount of acrylamide in thermally processed foods” whereby an example of a thermally processed food ingredient is roasted cacao beans among other things. The Examiner points out that Elder ‘054 discloses contacting asparagine with the enzyme asparaginase. The Examiner further notes that Elder ‘054 provides in Example 5 proof that acrylamide reduction was reduced by more than 99.9%. The Examiner then sums up by stating that it would have been obvious to one of ordinary skill in the art to have added an asparaginase enzyme to cocoa beans prior to heating/cooking in order to reduce the level of asparagine within the cocoa beans.

The Examiner bears the burden of factually supporting any *prima facie* conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. See Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fe. Cir. 1983). Distilling the invention down to the “gist” or “thrust” of an invention disregards the requirement of analyzing the subject matter “as a whole.” See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983). Inventors of unobvious compositions, such as those of the present invention, enjoy a *presumption* of non-obviousness, which must then be overcome by the Examiner establishing a case of *prima facie* obviousness by the appropriate standard. If the Examiner does not prove a *prima facie* case of unpatentability, then without more, the Applicant is entitled to grant of the patent. See In re Oetiker, 977 F.2d 1443.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all of the claim limitations.⁴

With regard to this obviousness rejection, Applicants respectfully disagree with the Examiner and assert that Elder '054 not only does not teach or suggest Applicants' invention but also fails to provide a reasonable expectation of success between its examples, particularly example no. 5, and the claimed subject matter of Elder '054, namely reducing the presence of acrylamide in thermally processed food. In so doing, Elder '054 has failed to appreciate the difficulty in adding or applying an asparagine-reducing enzyme to cocoa beans.

To begin, Applicants note that there are stark differences between 1) Applicants' cocoa beans and Elder's a simple sugar and amino acid and 2) reducing the levels of asparagine and/or acrylamide in cocoa beans versus that of simple sugar and amino acid. Looking carefully at the Example Nos. 1-5 of Elder '054, one is struck by the fact that the reduction of either asparagine or acrylamide is never achieved in food, or any edible, complex multi-celled structure like cocoa beans. Rather, Elder '054 merely adds simple sugar to amino acid in test vials, heats the materials, adds asparaginase and then records, essentially, the reaction of asparaginase to the sugar/amino acid combination in the way of reduced levels of acrylamide formed. More specifically, Elder '054 only shows the reduction of acrylamide in one example, namely, Example No. 5.

In Example No. 5, glucose is added to asparagine and then heated to form acrylamide. Next, asparaginase is added to the glucose/asparagine mix. Subsequently, the acrylamide levels are measured and compared with two untreated controls. Although a reduction in acrylamide is shown, Applicants assert that such experiments, without more, do not provide a reasonable expectation of success that one of skill in the art reading Elder '054 would be able to reduce asparagine/acrylamide in food, or any edible, complex multi-celled structure like cocoa beans. Elder's Example No. 5 is limited only to test vials with ingredients that cannot fairly be said to be cocoa beans or any other kind of food. Rather, the components glucose and asparagine represent the most basic building blocks of many foods but lack the complex structure of most foods, e.g., Applicants' cocoa beans.

Furthermore, Elder '054 only mentions that asparaginase can be used to come into "contact" with the simple sugar/amino acid combination. Other than putting asparaginase in the test tubes of Example No. 5, the nature of this "contact" is never explained, defined or taught. Applicants' "contact" of their asparagine-reducing enzyme is much more robust and definitive.⁵ Applicants' disclosure extends from

⁴ In re Vaeck, 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

⁵ Applicants' Specification at page 5, lines 32-35 to page 6, lines 1-2: "The enzyme may be added to the cocoa beans in any suitable form. For instance, the enzyme may be added as a powder or in the form of a solution. Furthermore, the enzyme may be added to the cocoa beans in any suitable manner, such as directly (for example, sprinkled, poured, or sprayed on the cocoa beans, or the cocoa beans can be soaked in an enzyme solution) or

page 5, line 32 to page 8, line 12 and details their break-through ability of adding an asparagine-reducing enzyme to cocoa beans to reduce asparagine levels in the beans. Such detailed addition is necessary because of complex multi-celled structures like cocoa beans. One of skill in the art knows that in order to penetrate the cell walls of, say, cocoa beans, much work and energy must be applied to the beans in order to reach the interior of the cocoa beans; i.e., the cite where asparagine is produced. Such difficulty is not appreciated by Elder '054.

As such Elder '054 has not taught or suggested Applicants' invention and furthermore has merely made unsubstantiated assertions of acrylamide reduction in food based on examples that do not teach or suggest the reduction of asparagine/acrylamide in cocoa beans or any other kind of food.

Applicants therefore respectfully request reconsideration and allowance of Claims 1-50 over the Examiner's 35 U.S.C. § 103(a) rejection in view of Elder '054.

With regard to Claims 17-18 the Examiner states that it would have been obvious to one of ordinary skill in the art to have packaged and appropriately labeled the food products produced by Elder '054. Such packaging techniques, notes the Examiner, were well known in the art. The Examiner further states that if Applicants' product claims are found to be allowable, then the article container claims 17-18 would also be allowable.

Applicants respectfully disagree with the Examiner's assertions. Applicants' respectfully assert that the Examiner is using the wrong test for nonobviousness. The test is whether the reference itself, herein Elder '054, or knowledge generally available to one of skill in the art teaches or suggests Applicants' invention. Applicants assert that neither condition has been met.

First, nothing in Elder '054 teaches or suggests an article of commerce that communicates the reduction or lowness of acrylamide in Applicants' cocoa beans or any other kind of food. As noted extensively herein, Elder '054 does not itself teach the reduction of acrylamide in cocoa beans, but merely a reaction of an enzyme with asparagine and simple sugar in a test vial.

Second, Applicants assert that one of skill in the art would not have been led to produce an article of commerce that communicates the reduction of acrylamide in cocoa beans or any other kind of food. Heretofore, the ability to reduce acrylamide in edible structures producing asparagine has never been accomplished until Applicants accomplished this reduction. Thus, there was no knowledge generally held available to one of skill in the art that such a claim, i.e., the reduction or lowness of acrylamide in food, was possible or even desired. Applicants point out that they claim an article of

indirectly. As used herein, "adding" the enzyme to the cocoa beans includes, but is not limited to, any means of bringing the asparagine and the enzyme together." [Applicants' disclosure is replete with this kind of detailed teaching.]

commerce having a message informing a consumer that the product has a reduced level of acrylamide. Applicants are not claiming a generic message or merely words on a package which is within the knowledge of one of ordinary skill in the art. Rather, Applicants' message is specific to a heretofore unobtainable function by any one of skill in the art save Applicants. Such a message is therefore not within the knowledge of one of ordinary skill in the art.

Thus, Applicants respectfully request reconsideration and allowance of Claims 17 and 18 over the Examiner's 35 U.S.C. § 103(a) rejection in view of Elder '054.

Double Patenting - Non-Statutory

Claims 17-18 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-14 of co-pending Application No. 10/603,978.

Applicants respectfully traverse these rejections. Applicants submit that the Examiner has failed to provide sufficient basis for asserting that the cited claims of U.S. Patent Application No. 10/603,978 teach or suggest the claims of the present application which are directed to reducing asparagines or acrylamide in food. Accordingly, it is respectfully requested that the obviousness-type double patenting rejections be withdrawn.

Claims 1-18 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20, 22-31 and 45-50 of co-pending Application No. 10/606,137.

Applicants respectfully traverse these rejections. Applicants submit that the Examiner has failed to provide sufficient basis for asserting that the cited claims of U.S. Patent Application No. 10/606,137 teach or suggest the claims of the present application which are directed to reducing asparagines or acrylamide in food. Accordingly, it is respectfully requested that the obviousness-type double patenting rejections be withdrawn.

SUMMARY

The rejections in the Office Action have been discussed and, Applicants believe, the proper discussions and/or amendments have been set forth to address the rejection.

In light of both the amendments and the discussions contained herein, Applicants respectfully request reconsideration of the rejection and its withdrawal.

Issuance of a Notice of Allowance at an early date is earnestly solicited.

Respectfully submitted,

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